

### **Remarks**

Applicants have canceled claims 1, 11, 13, 17-20, 24, and 29 without prejudice or disclaimer. Applicants have reserved the right to pursue the canceled subject matter in later-filed continuing applications. Accordingly, upon entry of the present amendment, original claims 25-28 and 30-45 will be pending.

The specification has been amended to include a section entitled "Brief Description of the Drawings" to describe Figures 1A-1C and Figure 2 of the invention. This description existed in the originally filed application, for example, on page 94, line 26 to page 95, line 17.

Accordingly, no new matter has been added.

#### **I. Information Disclosure Statement**

The Examiner has not considered References AF-AO, cited on the PTO-1449 form submitted by Applicants on September 22, 2003 because these references allegedly do not comply with the requirements of 37 C.F.R. § 1.98(a)(2). In particular, the Examiner alleges that the references fail to identify each publication by author. *See*, Paper No. 121103, page 3, paragraph 3a. Although Applicants believe that these references complied with the requirements of 37 C.F.R. § 1.98(a)(2) as submitted on September 22, 2003, Applicants have resubmitted an SB/08 form with the alleged missing information in the Supplemental Information Disclosure Statement submitted herewith. Accordingly, Applicants respectfully request consideration of these references.

#### **II. Objection to the Specification**

a. The Examiner has objected to the specification for lacking a section describing the figures of the instant application. *See*, Paper No. 121103, page 3, paragraph 4a. As requested by the Examiner, Applicants have amended the specification to include a section entitled "Brief Description of the Drawings" that describes Figures 1A-1C and Figure 2 of the instant application. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this objection.

b. Applicants acknowledge the Examiner's request to correct any errors of which Applicants may become aware in the specification. *See*, Paper No. 121103, page 4, paragraph 4b. Applicants are not currently aware of any errors in the specification that require correction; however, if any errors should come to the attention of the Applicants, Applicants will correct those errors.

### III. Objections to the Claims

The Examiner has objected to claims 11 and 29 due to informalities. *See*, Paper No. 121103, page 4, paragraph 5. However, Applicants have canceled claims 11 and 29, thus rendering these objections moot. Accordingly, Applicants request the Examiner to withdraw these objections.

### IV. Utility/Enablement Rejections Under 35 U.S.C. §§ 101/112

a. The Examiner has rejected claims 11 and 25-45 under 35 U.S.C. § 101, for alleged lack of a specific and substantial or well-established utility. In particular, the Examiner alleges that the

[i]nstant specification does not disclose or provide any evidence that points to an activity for the polypeptide of SEQ ID NO:222 and there is no art of record that discloses or suggests any activity for said polypeptide, therefore, the skilled artisan would not know how to use it.

*See*, Paper No. 121103, page 4-5, paragraph 6a.

Applicants respectfully disagree and traverse this rejection. Preliminarily, Applicants have canceled claims 11 and 29, thus rendering the rejection of these claims moot.

In order to find that an asserted utility is not specific or substantial or well-established, the burden is on the Examiner to make a *prima facie* showing that it more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the Applicant to be specific or substantial or well-established. *See*, M.P.E.P. § 2107.02(IV); Utility Examination Guidelines at 1098, col. 3. Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established; (2) support for factual finding relied upon in reaching this conclusion; and (3) and evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See id.*

Applicants contend that the Examiner has provided no evidence or support that (1) the logic underlying Applicants' assertions of utility is seriously flawed, (2) the facts upon which Applicants base the assertions of utility are inconsistent with the logic underlying the assertions, or that (3) the statements of asserted utility in the present application would be considered "false" by a person of ordinary skill in the art. The Examiner has simply provided generalized statements that the instant specification does not provide any evidence that the claimed polypeptide is indeed involved in any of utilities disclosed in the specification. (See, Paper No.121103, pages 4-6. section 6a).

Regarding substantial utility, the M.P.E.P. § 2107.01 on page 2100-32 states that,

Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders...would not be sufficient to define a specific utility for the compound.

Moreover, the M.P.E.P. states that if a utility has a "real-world" use that it should be considered to be substantial. In particular, M.P.E.P. § 2107.01 at page 2100-32 states "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, as least with regard to defining a 'substantial' utility."

Contrary to the Examiner's arguments, Applicants contend that the specification does set forth a specific, and substantial utility. For example, the specification describes how the polypeptides of the invention are primarily expressed in specific tumor tissues including endometrial, adenocarcinoma, and breast cancer, to name a few. See, specification, for example, at page 244, lines 13-15. Thus, the specification sets forth that the polypeptides of the invention may be useful, for example, in the diagnosis and/or treatment of those specific cancers. Applicants contend that the one of skill in the art would clearly find this asserted utility to be specific. In addition, since the diagnosis and/or treatment of such specific cancers is a certainly a "real-world" use, Applicants contend that the skilled artisan would also find the assertion of utility to be substantial.

In addition, Applicants respectfully point out that Applicants do not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in

treating humans where such a utility is asserted. Moreover, as stated in the M.P.E.P. § 2107.00 (III) at 2100-26, “[c]ourts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides ‘an immediate benefit’ and thus satisfies that utility requirement.” All that is required of Applicants is that there be a *reasonable* correlation between the biological activity and the asserted utility. *See Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980).

In view of the above, Applicants assert that one of ordinary skill in the art would consider Applicants’ asserted utility of the invention, to be *specific and substantial* and clearly would have no basis for considering these asserted utilities to be “false.” “When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown.” *Raytheon v. Roper*, 724 F.2d 951, 958 (Fed. Cir. 1983). Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 11 and 25-45 under 35 U.S.C. § 101 for alleged lack of utility.

b. The Examiner has also rejected claims 11 and 25-45, under 35 U.S.C. § 112, first paragraph, for lack of enablement (*See Paper No. 121103*, page 6, paragraph 6b). More particularly, the Examiner states that since the claimed invention is allegedly not supported by either a specific or substantial or well-established utility, one skilled in the art would not know how to use the claimed invention.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a credible, specific, and substantial utility. The Examiner “should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on ‘lack of utility’ basis unless a 35 U.S.C. § 101 rejection is proper.” M.P.E.P. § 2107(IV) at 2100-28 (Rev. 1, Feb. 2000). Since the claimed invention complies with the utility requirement of 35 U.S.C. § 101, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of the claims 11 and 25-45 under 35 U.S.C. § 112, first paragraph, based on alleged lack of utility of the claimed invention.

## **V. Enablement Rejections Under 35 U.S.C. § 112, First Paragraph**

a. The Examiner has rejected claim 11 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. In particular, the Examiner alleges that the specification does not adequately describe and enable a polypeptide with at least 95% identity to the polypeptide of SEQ ID NO:222. *See, Paper No. 121103*, page 6, third paragraph.

Applicants respectfully disagree and assert that the specification fully describes and enables polypeptide with at least 95% identity to the polypeptide of SEQ ID NO:222. However, in the interest of facilitating prosecution, and in no way in acquiescence to the Examiner's rejection, Applicants have canceled claim 11, thereby rendering the Examiner's rejection moot. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of claim 11 under 35 U.S.C. § 112, first paragraph.

b. The Examiner has rejected claims 36-45 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. In particular, the Examiner contends that a statement "that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor will be irrevocably removed upon the granting of a patent" is required. *See*, Paper No. 121103, page 8, second paragraph.

With respect to the Budapest Treaty and the availability of the deposit to the public, Applicants' representative hereby gives the following assurance by signature below:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit of the HOGCK20 cDNA, designated as DNA plasmid PS-086, was made on May 7, 1998, accepted by the ATCC, and given ATCC Accession Number 209853. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 209853 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number 209853 is enclosed herewith as Exhibit A.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 36-45 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement.


### Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

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Respectfully submitted,

By   
Janet M. Martineau  
Registration No.: 46,903  
HUMAN GENOME SCIENCES, INC.  
14200 Shady Grove Road  
Rockville, Maryland 20850  
(301) 315-2723

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